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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA INC. Plaintiffs, v. PERRIGO COMPANY PLC, PERRIGO COMPANY, L. PERRIGO COMPANY, and PADDOCK LABORATORIES, LLC, Defendants.	Civil Action No. 3:15-cv-01057 (MLC)(TJB) **ANSWER, DEFENSES AND COUNTERCLAIMS OF DEFENDANTS PERRIGO COMPANY PLC, PERRIGO COMPANY, AND L. PERRIGO COMPANY**

Defendants Perrigo Company plc , Perrigo Company, and L. Perrigo Company (collectively, "Defendants"), by their attorneys, hereby Answer the Complaint of AstraZeneca AB, Aktiebolaget Hässle, AstraZeneca LP, and Zeneca Inc. (collectively, "Plaintiffs") as follows:

NATURE OF THE ACTION

1. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Plaintiffs' Complaint purports to recite a civil action for patent infringement, and in particular under 35 U.S.C. § 271(e). Defendants further admit that this action relates to Abbreviated New Drug Application ("ANDA") No. 207193 filed by or for the benefit of Defendants with the U.S. Food and Drug Administration ("FDA"). Defendants further admit that the reference listed drug identified in ANDA No. 207193 is NEXIUM 24HR®. Defendants deny the remaining allegations in paragraph 1 of the Complaint.

THE PARTIES

2. Defendants are without sufficient knowledge or information to admit or deny the allegations in Paragraph 2 of the Complaint, and therefore deny same.

3. Defendants are without sufficient knowledge or information to admit or deny the allegations in Paragraph 3 of the Complaint, and therefore deny same.

4. Defendants are without sufficient knowledge or information to admit or deny the allegations in Paragraph 4 of the Complaint, and therefore deny same.

5. Defendants are without sufficient knowledge or information to admit or deny the allegations in Paragraph 5 of the Complaint, and therefore deny same.

6. Admitted.

7. Admitted.

8. Defendants admit that L. Perrigo Company is a company organized and existing under the laws of Michigan. Defendants deny the remaining allegations in paragraph 8 of the Complaint.

9. Admitted.

10. Admitted.

11. Admitted.

12. Admitted.

13. Defendants admit that Perrigo Company plc, either directly or through one or more of its wholly owned subsidiaries and/or agents, develops and manufactures generic drug products for sale in the United States. Defendants deny the remaining allegations in paragraph 13 of the Complaint.

14. Defendants admit that Perrigo Company plc, either directly or through one or more of its wholly owned subsidiaries and/or agents, develops and manufactures generic drug products for sale in the United States. Defendants deny the remaining allegations in paragraph 14 of the Complaint.

BACKGROUND

The NDA

15. Defendants lack knowledge and information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore deny same.

The Patents-in-Suit

16. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that U.S. Patent No. 6,369,085 ("the '085

patent") is entitled "Form of S-Omeprazole". Defendants further admit that, according to its face, the '085 patent issued on April 9, 2002. Defendants further admit that the '085 patent identifies on its face, Hanna Cotton, Anders Kronström, Anders Mattson, and Eva Möller as the purported inventors. Defendants admit that Exhibit A purports to be a copy of the '085 patent. Defendants deny the remaining allegations in paragraph 16 of the Complaint, including any suggestion that the '085 patent was duly and legally issued.

17. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the '085 patent identifies on its face, AstraZeneca AB as the purported assignee. Defendants are without sufficient knowledge or information to admit or deny the allegations in Paragraph 17 of the Complaint, and therefore deny same.

18. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that U.S. Patent No. 7,411,070 ("the '070 patent") is entitled "Form of S-Omeprazole". Defendants further admit that, according to its face, the '070 patent issued on August 12, 2008. Defendants further admit that the '070 patent identifies on its face, Hanna Cotton, Anders Kronström, Anders Mattson, and Eva Möller as the purported inventors. Defendants admit that Exhibit B purports to be a copy of the '070 patent. Defendants deny the remaining allegations in paragraph 18 of the Complaint, including any suggestion that the '070 patent was duly and legally issued.

19. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the '070 patent identifies on its face, AstraZeneca AB as the purported assignee. Defendants are without sufficient knowledge or

information to admit or deny the allegations in Paragraph 19 of the Complaint, and therefore deny same.

The ANDA

20. Defendants admit that ANDA No. 207193 was submitted to FDA to obtain approval for the commercial manufacture, use, or sale of esomeprazole magnesium delayed-release capsules, 20 mg. Defendants deny the remaining allegations in paragraph 20 of the Complaint.

21. Defendants admit that by letter dated December 22, 2014, Plaintiffs were notified pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 that ANDA No. 207193 was submitted to FDA. Defendants further admit that the letter states that ANDA No. 207193 seeks approval to engage in the commercial manufacture, use, or sale of esomeprazole magnesium delayed-release capsules, 20 mg. Defendants deny the remaining allegations in paragraph 21 of the Complaint.

JURISDICTION AND VENUE

22. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Plaintiffs' complaint is for alleged patent infringement, but denies that Plaintiffs are entitled to such relief. Defendants further admit that this Court has subject matter jurisdiction over Plaintiffs' infringement claim. Defendants deny the remaining allegations in paragraph 22 of the Complaint.

23. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction solely for purposes of this action only. Defendants deny the remaining allegations in paragraph 23 of the Complaint.

24. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction solely for purposes of this action only. Defendants deny the remaining allegations in paragraph 24 of the Complaint.

25. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction solely for purposes of this action only. Defendants deny the remaining allegations in paragraph 25 of the Complaint.

26. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction solely for purposes of this action only. Defendants deny the remaining allegations in paragraph 26 of the Complaint.

27. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction solely for purposes of this action only. Defendants deny the remaining allegations in paragraph 27 of the Complaint.

28. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction solely for purposes of this action only. Defendants deny the remaining allegations in paragraph 28 of the Complaint.

29. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction solely for purposes of this action only. Defendants deny the remaining allegations in paragraph 29 of the Complaint.

30. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction solely for purposes of this action only. Defendants deny the remaining allegations in paragraph 30 of the Complaint.

31. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction solely for purposes of this action only. Defendants deny the remaining allegations in paragraph 31 of the Complaint.

32. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest venue solely for purposes of this action only. Defendants deny the remaining allegations in paragraph 32 of the Complaint.

COUNT 1: INFRINGEMENT OF THE '085 PATENT

33. Defendants restate and incorporate each of their responses to paragraphs 1-32 as if fully set forth herein.

34. Defendants admit that ANDA No. 207193 was submitted to FDA to obtain approval to commercially manufacture, use and sell esomeprazole magnesium delayed-release capsules, 20 mg, prior to the expiration of the '085 patent. Defendants deny the remaining allegations in paragraph 34 of the Complaint.

35. Defendants admit that by letter dated December 22, 2014, Plaintiffs were notified that a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") with respect to the '085 patent was submitted to FDA. Defendants further admit that the letter states, in part, the '085 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of esomeprazole magnesium delayed-release capsules, 20 mg, described in ANDA No. 207193. Defendants deny the remaining allegations in paragraph 35 of the Complaint.

36. Denied.

37. Denied.

38. Denied.

39. Denied.

40. Denied.

COUNT 2: INFRINGEMENT OF THE '070 PATENT

41. Defendants restate and incorporate each of their responses to paragraphs 1-32 as if fully set forth herein.

42. Defendants admit that ANDA No. 207193 was submitted to FDA seeking approval to commercially manufacture, use and sell esomeprazole magnesium delayed-release capsules, 20 mg, prior to the expiration of the '070 patent. Defendants deny the remaining allegations in paragraph 42 of the Complaint.

43. Defendants admit that by letter dated December 22, 2014, Plaintiffs were notified that a Paragraph IV certification with respect to the '070 patent was submitted to FDA. Defendants further admit that the letter states, in part, the '070 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of esomeprazole magnesium delayed-release capsules, 20 mg, described in ANDA No. 207193. Defendants deny the remaining allegations in paragraph 43 of the Complaint.

44. Denied.

45. Denied.

46. Denied.

47. Denied.

48. Denied.

PRAYER FOR RELIEF

Defendants deny all allegations not specifically admitted herein, and further denies that Plaintiffs are entitled to the judgment and relief requested in the Prayer for Relief set forth in the Complaint or to any other relief.

AFFIRMATIVE AND SEPARATE DEFENSES

Without prejudice to the denials set forth in its responses to paragraphs 1 through 48 of the Complaint, Defendants allege the following affirmative defenses. Defendants expressly reserve the right to allege additional defenses as they become known through the course of discovery. Defendants do not intend to hereby assume the burden of proof with respect to those matters as to which, pursuant to law, Plaintiffs bear the burden of proof.

First Defense

(Noninfringement of the '085 Patent)

The manufacture, use or sale of esomeprazole magnesium delayed-release capsules, 20 mg, described in ANDA No. 207193 has not infringed, does not infringe, and would not, if marketed, sold or used, infringe any valid and enforceable claim of the '085 patent.

Second Defense

(Invalidity of the '085 Patent)

The '085 patent, including all claims thereof, is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and/or 112.

Third Defense

(Noninfringement of the '070 Patent)

The manufacture, use or sale of esomeprazole magnesium delayed-release capsules, 20 mg, described in ANDA No. 207193 has not infringed, does not infringe, and would not, if marketed, sold or used, infringe any valid and enforceable claim of the '070 patent.

Fourth Defense

(Invalidity of the '070 Patent)

The '070 patent, including all claims thereof, is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and/or 112.

Fifth Defense

(Failure to State a Claim)

Plaintiffs fail to state a claim upon which relief can be granted.

Sixth Defense

(Additional Defenses or Counterclaims)

Defendants reserve the right to assert any additional defenses or counterclaims that discovery may reveal, as Plaintiffs have not begun producing discovery to Defendants and Defendants have not yet had the opportunity to pursue relevant third-party discovery.

COUNTERCLAIMS

Defendants/Counterclaim Plaintiffs Perrigo Company plc, Perrigo Company, and L. Perrigo Company (collectively, "Defendants/Counterclaim Plaintiffs" or "Defendants") hereby assert counterclaims against Plaintiffs/Counterclaim Defendants AstraZeneca AB ("AZ AB"), Aktiebolaget Hässle, AstraZeneca LP ("AZ LP"), and Zeneca Inc. ("Zeneca") (collectively, "Plaintiffs/Counterclaim Defendants" or "Plaintiffs") as follows:

Parties

1. Perrigo plc is a company organized and existing under the laws of Ireland with its principal place of business at Treasury Building, Lower Grand Canal St., Dublin 2, Ireland.

2. Perrigo Company is a company organized and existing under the laws of Michigan with its principal place of business at 515 Eastern Avenue, Allegan, Michigan 49010.

3. L. Perrigo Company is a company organized and existing under the laws of Michigan with its principal place of business at 515 Eastern Avenue, Allegan, Michigan 49010.

4. On information and belief, AZ AB purports to be a corporation operating and existing under the laws of Sweden, with its principal place of business at Södertälje, Sweden.

5. On information and belief, Aktiebolaget Hässle is a corporation organized and exiting under the laws of Sweden, having its principal place of business at Mölndal, Sweden.

6. On information and belief, AZ LP is a limited partnership operating and existing under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803.

7. On information and belief, Zeneca is a Delaware corporation having its principal place of business at Wilmington, Delaware.

Jurisdiction and Venue

8. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 et seq.; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA") (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

9. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under the MMA (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

10. This Court has personal jurisdiction over Plaintiffs/Counterclaim Defendants because Plaintiffs/Counterclaims Defendants availed themselves of the rights and privileges of

this forum by suing Defendants/Counterclaim Plaintiffs in this District, and, on information and belief, because Plaintiffs/Counterclaim Defendants conduct substantial business in, and have regular systematic contact with, this District.

11. Venue is proper under 28 U.S.C. §§ 1391 and 1400(b).

Background

A. FDA Approval of New Brand-Name Drugs

12. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 et seq., as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (commonly known as the "Hatch-Waxman Amendments" or "Hatch-Waxman"), and as further amended by Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA"), sets forth the rules that the U.S. Food and Drug Administration ("FDA") follows when considering whether to approve both brand-name and generic drugs.

13. Under the FFDCA, as amended by Hatch-Waxman and the MMA, an applicant seeking to market a new brand-name drug that has not been previously approved must prepare a New Drug Application ("NDA") for consideration by FDA. *See* 21 U.S.C. § 355.

14. An NDA must include, among other things, the number of any patent that claims the "drug" or a "method of using [the] drug" for which the NDA was submitted. *See* 21 U.S.C. §§ 355(b)(1), (c)(2); 21 C.F.R. §§ 314.53(b), (c)(2).

15. Upon approval of the NDA, the FDA publishes patent information for the approved drug in "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii).

B. Generic Competition – Abbreviated New Drug Applications

16. In 1984, Congress enacted the Hatch-Waxman Amendments to the FFDCA. Congress passed Hatch-Waxman, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition. Under Hatch-Waxman, a generic manufacturer submits what is called an Abbreviated New Drug Application ("ANDA").

17. To receive approval of its ANDA, an applicant must, *inter alia*, show that its generic drug is "bioequivalent" to the listed reference drug. *See* 21 U.S.C. § 355(j)(4)(F).

18. When filing an ANDA seeking approval of a generic version of a drug listed in the Orange Book, the ANDA applicant must also "certify" that any patent information properly listed in the Orange Book does not preclude FDA approval of a generic version of the drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

19. When seeking FDA approval to market prior to expiration of patents listed in the Orange Book, an ANDA applicant must submit a so-called "paragraph IV" certification asserting that the listed patent is invalid, unenforceable, and/or will not be infringed. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

20. An applicant submitting an ANDA containing a paragraph IV certification must notify both the patent holder and NDA holder of its paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(B).

21. If the patent holder brings suit within 45 days of receiving the notice required by 21 U.S.C. § 355(j)(2)(B), FDA cannot give final approval to the ANDA for 30 months, unless the district court enters an order shortening that period or the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action

for patent infringement or invalidity) before expiration of such 30 month period. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

C. NEXIUM 24HR® Esomeprazole Magnesium Delayed-Release Capsules, 20 mg and The Patents-In-Suit

22. According to the electronic records of the U.S. Patent and Trademark Office ("USPTO"), U.S. Patent No. 6,369,085 ("the '085 patent") issued on or about April 9, 2002 to inventors Hanna Cotton, Anders Kronström, Anders Mattson, and Eva Möller and is assigned to AZ AB. The '085 patent is entitled "Form of S-Omeprazole."

23. According to the electronic records of the USPTO, U.S. Patent No. 7,411,070 ("the '070 patent") issued on or about August 12, 2008 to inventors Hanna Cotton, Anders Kronström, Anders Mattson, and Eva Möller and is assigned to AZ AB. The '070 patent is entitled "Form of S-Omeprazole."

24. On information and belief, Zeneca has exclusive rights in the United States to market and sell products covered by the '085 and '070 patents.

25. On information and belief, AZ LP is the holder of NDA No. 204655 for NEXIUM 24HR® Esomeprazole Magnesium Delayed-Release Capsules, 20 mg.

26. On information and belief, Plaintiffs/Counterclaim Defendants submitted information on the '085 and '070 patents to FDA for listing in the Orange Book. By virtue of that submission, FDA listed the '085 and '070 patents in the Orange Book in connection with the approved NDA for NEXIUM 24HR® Esomeprazole Magnesium Delayed-Release Capsules, 20 mg.

D. ANDA No. 207193 for Esomeprazole Delayed-Release Capsules, 20 mg

27. Defendants filed an ANDA with the FDA seeking approval for esomeprazole magnesium delayed-release capsules, 20 mg. FDA assigned Defendants' ANDA No. 207193 ("Defendants' ANDA").

28. Defendants' ANDA references AZ LP's NDA No. 204655.

29. Because Defendants' ANDA seeks FDA approval to market esomeprazole magnesium delayed-release capsules, 20 mg, before expiration of the '085 and '070 patents listed in the Orange Book, Defendants' ANDA includes a paragraph IV certification for the '085 and '070 patents.

30. In accordance with 21 U.S.C. § 355(j)(2)(B), notice was provided to, *inter alia*, Plaintiffs that ANDA No. 207193 was submitted to FDA with a paragraph IV certification to the '085 and '070 patents. This notice included a detailed statement setting forth factual and legal bases as to why the '085 and '070 patent claims will not be infringed by the manufacture, use, offer for sale, sale, or importation of the esomeprazole magnesium delayed-release capsules, 20 mg, described in Defendants' ANDA. The notice also detailed why the '085 and '070 patents are invalid, and, *inter alia*, expressly reserved the right to raise additional defenses including noninfringement, invalidity, and unenforceability in the event that suit was filed on the '085 and '070 patents.

31. The esomeprazole magnesium delayed-release capsules, 20 mg, described in Defendants' ANDA does not infringe any valid or enforceable claim of the '085 patent.

32. The esomeprazole magnesium delayed-release capsules, 20 mg, described in Defendants' ANDA does not infringe any valid or enforceable claim of the '070 patent.

33. Following receipt of notice of paragraph IV certification to the '085 and '070 patents, Plaintiffs sued, *inter alia*, Defendants for infringement of the '085 and '070 patents in this District.

First Counterclaim

(Declaration of Noninfringement of the '085 Patent)

34. Defendants/Counterclaim Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-33.

35. A present, genuine, and justiciable controversy exists between Defendants/Counterclaim Plaintiffs and Plaintiffs/Counterclaim Defendants regarding, *inter alia*, the issue of whether the manufacture, use, offer for sale, or sale of the esomeprazole magnesium delayed-release capsules, 20 mg, described in Defendants' ANDA would infringe any valid or enforceable claim of the '085 patent.

36. The manufacture, use, offer for sale, or sale of the esomeprazole magnesium delayed-release capsules, 20 mg, described in Defendants' ANDA would not infringe any valid or enforceable claim of the '085 patent.

37. Defendants/Counterclaim Plaintiffs are is entitled to a declaration that the manufacture, use, offer for sale, or sale of the esomeprazole magnesium delayed-release capsules, 20 mg, described in Defendants' ANDA would not infringe any valid or enforceable claim of the '085 patent.

Second Counterclaim

(Declaration of Invalidity of the '085 Patent)

38. Defendants/Counterclaim Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-37.

39. A present, genuine, and justiciable controversy exists between Defendants/Counterclaim Plaintiffs and Plaintiffs/Counterclaim Defendants regarding, *inter alia*, the invalidity of the '085 patent.

40. The '085 patent is invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

41. Defendants/Counterclaim Plaintiffs are entitled to a declaration that the '085 patent is invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

Third Counterclaim

(Declaration of Noninfringement of the '070 Patent)

42. Defendants/Counterclaim Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-41.

43. A present, genuine, and justiciable controversy exists between Defendants/Counterclaim Plaintiffs and Plaintiffs/Counterclaim Defendants regarding, *inter alia*, the issue of whether the manufacture, use, offer for sale, or sale of the esomeprazole magnesium delayed-release capsules, 20 mg, described in Defendants' ANDA would infringe any valid or enforceable claim of the '070 patent.

44. The manufacture, use, offer for sale, or sale of the esomeprazole magnesium delayed-release capsules, 20 mg, described in Defendants' ANDA would not infringe any valid or enforceable claim of the '070 patent.

45. Defendants/Counterclaim Plaintiffs are entitled to a declaration that the manufacture, use, offer for sale, or sale of the esomeprazole magnesium delayed-release

capsules, 20 mg, described in Defendants' ANDA would not infringe any valid or enforceable claim of the '070 patent.

Fourth Counterclaim

(Declaration of Invalidity of the '070 Patent)

46. Defendants/Counterclaim Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-45.

47. A present, genuine, and justiciable controversy exists between Defendants/Counterclaim Plaintiffs and Plaintiffs/Counterclaim Defendants regarding, *inter alia*, the invalidity of the '070 patent.

48. The '070 patent is invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

49. Defendants/Counterclaim Plaintiffs are entitled to a declaration that the '070 patent is invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

REQUEST FOR RELIEF

WHEREFORE, Defendants/Counterclaim Plaintiffs Perrigo Company plc, Perrigo Company, and L. Perrigo Company pray that this Court enter judgment against Plaintiffs/Counterclaim Defendants AstraZeneca AB, Aktiebolaget Hässle, AstraZeneca LP, and Zeneca Inc. as follows:

(a) declaring that the manufacture, sale, offer for sale, use or importation of the esomeprazole magnesium delayed-release capsules, 20 mg, described in Defendants' ANDA does not and will not infringe, either literally or under the doctrine of equivalents, directly or indirectly, either by inducement or contributorily, any valid or enforceable claim of the '085 patent;

(b) declaring that the manufacture, sale, offer for sale, use or importation of the esomeprazole magnesium delayed-release capsules, 20 mg, described in

Defendants' ANDA does not and will not infringe, either literally or under the doctrine of equivalents, directly or indirectly, either by inducement or contributorily, any valid or enforceable claim of the '070 patent;

(c) declaring that the '085 patent is invalid;

(d) declaring that the '070 patent is invalid;

(e) ordering that Plaintiffs' complaint be dismissed with prejudice and judgment entered in favor of Defendants;

(f) declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Defendants attorney fees, costs, and expenses in this action; and

(g) awarding Defendants any further and additional relief as the Court deems just and proper.

Dated: April 1, 2015

s/ Melissa E. Flax
Melissa E. Flax
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CERTIFICATION PURSUANT TO L. CIV. R. 11.2 & 40.1

On behalf of Defendants Perrigo Company plc, Perrigo Company, and L. Perrigo Company, I hereby certify that the following pending actions are related:

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC. v. MYLAN LABORATORIES LTD. and MYLAN, INC.*, C.A. No. 3:12-cv-01378- MLC-TJB (District of New Jersey).

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC. v. WATSON LABORATORIES, INC. – FLORIDA*, C.A. No. 3:13-cv-01669-MLC-TJB (District of New Jersey).

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC. and KBI-E INC. v. WOCKHARDT LIMITED and WOCKHARDT USA LLC*, C.A. No. 3:13-cv-04854-MLC-TJB (District of New Jersey).

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC v. HANMI USA, INC., HANMI PHARMACEUTICAL CO., LTD., HANMI FINE CHEMICAL CO., LTD, and HANMI HOLDINGS CO., LTD.*, C.A. No. 3:11-cv-00760-JAP-TJB (District of New Jersey).

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE,; ASTRAZENECA LP, KBI INC., and KBI-E INC. v. AUROBINDO PHARMA LIMITED and AUROBINDO PHARMA USA Inc.*, C.A. No. 3:13-cv-7298-MLC-TJB (District of New Jersey).

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP; KBI INC., and KBI-E INC. v. KREMERS URBAN PHARMACEUTICALS, KREMERS URBAN DEVELOPMENT CO., and KREMERS URBAN LLC*, C.A. No. 3:13-cv-7299-MLCTJB (District of New Jersey).

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA INC. v. ACTAVIS LABORATORIES FL, INC., and ACTAVIS PHARMA, INC.*, C.A. No. 3:14-cv-07263-MLC-TJB (District of New Jersey).

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA INC. v. ZYDUS PHARMACEUTICALS (USA) INC. and CADILA HEALTHCARE LTD.*, C.A. No. 3:14-cv-04782-MLC-TJB (District of New Jersey).

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA INC. v. ANDRX LABS, LLC, ANDRX CORPORATION, and ACTAVIS, INC.*, C.A. No. 3:14-cv-08030-MLC-TJB (District of New Jersey).

The foregoing cases involve NEXIUM® and/or NEXIUM 24HR®, products marketed by AstraZeneca that contain an esomeprazole magnesium formulation. The above cases have all been assigned to Hon. Mary L. Cooper U.S.D.J.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court in this jurisdiction, or of any pending arbitration or administrative proceedings.

Dated: April 1, 2015

s/ Melissa E. Flax

Melissa E. Flax
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CERTIFICATION PURSUANT TO L. CIV. R. 201.1

Pursuant to Local Civil Rule 201.1, the undersigned counsel for Defendants/Counterclaim Plaintiffs Perrigo Company plc, Perrigo Company, and L. Perrigo Company certifies that the counterclaims herein seek injunctive relief, not damages. This action is, therefore, not appropriate for compulsory arbitration.

Dated: April 1, 2015

s/ Melissa E. Flax

Melissa E. Flax
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